I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 535603597 US, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: February 13, 2006 Signature: Georgina Matos
(Georgina Matos)

Docket No.: 311772000600
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Richard C. ALLEN et al.

Confirmation No.: 8803

Application No.: 09/289,576

Art Unit: 1632

Filed: April 9, 1999

Examiner: A. Falk

For: METHODS OF TREATING SCHIZOPHRENIA

DECLARATION OF MICHAEL CORNFELDT UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Michael CORNFELDT, declare as follows:

1) I am a listed inventor of and familiar with the subject matter claimed in the above-referenced patent application (Serial No. 09/289,576). A copy of my curriculum vitae, describing my background and qualifications, accompanies this Declaration as Attachment A.

2) I have read and am familiar with the Office Action mailed December 15, 2004 ("the Office Action") in regard to the above-referenced patent application (Serial No. 09/289,576).

3) In the Office Action, the Examiner contends that the specification, when considered in conjunction with the state of the art as it existed as of the application's filing date of April 9, 1999, was not sufficient to allow one of ordinary skill at that time to use the claimed method such that it

would give a therapeutic effect on the negative symptoms and cognitive deficits of schizophrenia, without undue experimentation. I have addressed this issue in paragraphs 4-13 below.

4) The instant application claims a method of treating negative symptoms or the cognitive defects associated with schizophrenia. Specifically, cells producing dopamine or a dopamine precursor such as retinal pigmented epithelial (RPE) cells are implanted into the prefrontal cortex, in order to provide dopamine to this region.

5) Schizophrenia is characterized by two main types of symptoms. "Positive" symptoms include delusions or hallucinations, while the negative/cognitive deficit symptom complex includes affective flattening, alogia, avolition, anhedonia (loss of interest or pleasure), social withdrawal and apathy.

6) Positive and negative/deficit symptoms are thought to have opposite causes. Although positive symptoms are thought to be caused by *excess* dopamine function in the mesolimbic area of the brain, negative symptoms are thought to be caused by *decreased* dopamine tone in another area of the brain, *i.e.*, the prefrontal cortex. *See, e.g.*, Davis *et al.*, Am. J. Psychiatry 148:1474-1486 (1991) (of record), at abstract; page 1479, second column; and page 1481, second column. For example, Brozoski *et al.* demonstrated in a rhesus monkey model that when the prefrontal cortex was selectively depleted of dopamine by local injection of the neurotoxin 6-OHDA, cognitive function declined. Brozoski *et al.*, Science, 205:1929-931 (1979) (of record).

7) Positive symptoms may sometimes be treated by dopamine antagonists. There is no established therapy yet for the treatment of the negative/cognitive deficit symptom complex. However, administration of dopamine (or its precursors) has been shown to ameliorate these symptoms. Inanaga *et al.*, Folia Psychiatr Neurol Jpn (1975), 29:123-43 (of record). In addition, administration of dopamine or its precursors reverses cognitive defects caused by loss of dopamine in the *prefrontal cortex* specifically. For instance, Brozoski *et al.* showed that the dopamine precursor levodopa reversed cognitive impairment caused by neurotoxin-induced dopamine depletion in the prefrontal cortex of monkeys. Brozoski *et al.*, at page 931, second column. Similarly, Fernandez-

Ruiz et al. showed that the dopamine precursor L-DOPA significantly improved prefrontal cortex-related activities such as memory and spatial delayed response tasks. Fernandez-Ruiz et al., Psychopharmacology, 147: 104-107 (1999). Fernandez-Ruiz et al. treated rhesus monkeys with a dopaminergic neurotoxin MPTP in order to mimic cognitive defects often seen in Parkinson's Disease. Fernandez-Ruiz et al. noted that MPTP causes disruption of the "prefronto-striatal system," which includes the prefrontal cortex as well as the striatum. Fernandez-Ruiz et al., at page 104, second column. Fernandez-Ruiz et al. also noted that the prefrontal cortex in addition to the striatum is impaired in both Parkinson's disease patients and MPTP-treated monkeys. Id. Fernandez-Ruiz et al. administered L-DOPA systemically to the test monkeys through oral administration so that L-DOPA reached the prefrontal cortex as well as the striatum. Fernandez-Ruiz et al., at page 105, first column. Fernandez-Ruiz et al. concluded that "L-DOPA reverses the MPTP-induced impairment by acting on *both* components of the fronto-striatal system" - that is, both the prefrontal cortex and the striatum. Fernandez-Ruiz et al., at page 107, first column (emphasis added). Fernandez-Ruiz et al. therefore demonstrate that administration of the dopamine precursor L-DOPA has a therapeutic effect on cognitive defects caused by disruption of the fronto-striatal system, including the prefrontal cortex.

8) The Office Action contends that "studies that teach administration of L-DOPA do not provide specific guidance with regard to the claimed invention which is quite distinct, involving administration of cells that produce dopamine or a dopamine precursor." Office Action at page 4, first paragraph. Actually, the preferred cells of the invention (RPE cells) themselves produce L-DOPA. Watts *et al.*, J Neur. Tr. Suppl. 65:215 (2003), at page 217. In any case, I have addressed this point in paragraphs 9-13 below.

9) Cell-based dopamine replenishment had been effectively used before April 1999 in treating animal models of dopamine deficiency disorders, such as Parkinson's disease. For instance, Subramanian *et al.* found that the implantation of dopamine-producing RPE cells of the invention into the brain of monkey models of Parkinson's disease reversed parkinsonian symptoms, just as administration of L-DOPA itself would. The animals were treated with 10,000 RPE cells/site at 5 sites (*i.e.*, 5×10^5 cells in total). *See* Subramanian et al. (1998) Abs. Amer. Soc. for Neural Transpl.,

2-5; Subramanian et al. (1998) Abs. 5th International Cong. Parkinson's Disease and Movement Disorders, New York; Subramanian et al. (1999) Parkinsonism and Related Disorders, 5, S111.

10) The Office Action asserts that instant application fails to teach the number of cells that must be administered to provide enough dopamine to effectively treat schizophrenia. However, the application provides clear guidelines on how many cells to administer. See, e.g., page 23, lines 7-10 (10^3-10^7 cells, preferably 10^5 to 10^6 cells, should be used).

11) I am a co-author of a post-filing publication by Watts et al., which discloses that dopamine-producing RPE cells implanted into the brain of human patients resulted in long term amelioration of Parkinson's disease symptoms. Watts et al., Neurology 56, Suppl. 3, Abstract P04.102 (Apr 2001) (of record). Specifically, Watts et al. demonstrated that the implantation of 325,000 dopamine-producing RPE cells into the brain of parkinsonian patients produced "long term amelioration of motor and behavioural deficits." *Id.* Watts et al. also reported that the therapeutic effects of RPE cell transplantation had lasted for 24 months as of 2003. In fact, the therapeutic effects are still evident in these patients today, more than four years later. Watts et al. found that the transplantation of RPE cell was as therapeutically effective as the administration of L-DOPA itself. Compare Watts et al. (2003) (transplantation of 325,000 RPE cells into the brain of parkinsonian patients improved UPDRS-Motor scores by approx. 30-50%) with Rascol et al., Mov Disord. 13(1):39-45 (1998) (disclosing that oral doses of levodopa improved UPDRS-Motor scores of parkinsonian patients by 44%).

12) Watts et al. used the cell implantation methods and parameters taught in the instant application and provide post-filing evidence that these teachings of the application are correct. The number of cells used by Watts et al. on humans (i.e., 3×10^5 cells) falls within the guidelines of the instant application (which states that 10^3-10^7 cells, preferably 10^5-10^6 cells, should be used). Watts et al. attached the preferred cells of the invention (RPE cells) to the preferred microcarrier of the invention (gelatin microbeads of 100 μm diameter), and implanted these cells into Parkinson's disease patients using the methods taught in the invention (MRI-guided stereotaxic surgery).

13) Although the Office Action acknowledges that the art at the time of filing teaches cell-based dopamine replacement therapy for *Parkinson's disease*, the Office Action contends that this teaching does not provide guidance for treatment of *schizophrenia*, which has its own distinct etiology. However, **doses of dopamine (or dopamine precursors) that are effective to treat Parkinson's disease are more than sufficient to treat the cognitive defects and negative symptoms of schizophrenia. For instance, the oral dosage of levodopa used for Parkinson's disease is the same as or higher than the effective dosage required for schizophrenia.** *Compare* Physician's Desk Reference (oral doses of 1-8 gm of levodopa for Parkinson's disease) with Inanaga *et al.*, Folia Psychiatr Neurol Jpn (1975), 29:123-43 (oral doses of 400-1200 mgs of levodopa are effective to treat negative symptoms and/or cognitive deficits of schizophrenia). **Thus, any number of cells shown to provide sufficient dopamine to produce a therapeutic effect in Parkinson's disease should be sufficient to treat schizophrenia**. The application's guidelines regarding the number of cells to use cover the number of cells shown by Watts *et al.* to be effective in ameliorating motor and behavioral defects associated with Parkinson's disease. Thus the application does provide guidance that is sufficient for the treatment of the negative symptoms and/or cognitive defects of schizophrenia.

14) Based upon my own experience and knowledge, methods of implanting cells into the brain and the techniques of stereotaxic surgery were well established, allowing implantation into any part of the brain with great control and precision as of April 9, 1999. Although the negative/deficit symptom complex of schizophrenia relates to a different area of the brain (*i.e.*, the prefrontal cortex) from the area affected in Parkinson's disease (*i.e.*, the striatum), the instant application clearly discloses that the cells must be administered to the prefrontal cortex, specifically the dorsolateral prefrontal cortex. *See, e.g.*, page 12, line 11. Through my own experience of cell implantation into the brain, I can attest that by April 1999, implantation of cells into the dorsolateral prefrontal cortex was an established technique.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are

punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Executed at Somerville, New Jersey, on February 10, 2006.

Michael L. Cornfeldt

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SCIENTIFIC RESEARCH MANAGEMENT and ADMINISTRATION

Pharmaceuticals Biotechnology Environmental Sciences Ag Chemicals

Over thirty years of experience in neuroscience, psychopharmacology, biology, molecular biology and pharmacology in the pharmaceutical industry. Hands on research, research management and policy and strategy management. Thoroughly experienced in managing the entire research cycle from compound discovery through development, pre-clinical and strategic marketing. Participated in twelve INDs.

PROFESSIONAL EXPERIENCE

2004 – Present **TITAN PHARMACEUTICALS, INC.**, Somerville, New Jersey

Sr. Director of Product Research, Cell Therapy. Responsibilities cover a broad area of drug research and development activities, which include support of CMC in the development of comparability assays for lots, monitoring surgical clinical sites and research support of the project teams. Directing and monitoring the research activities is a continued responsibility. The scope of this position requires interaction with regulatory, internal and external, board members, corporate partners and contractors and various academic advisor and collaborators.

1999 - 2004 **TITAN PHARMACEUTICALS, INC,** Somerville, New Jersey

Director of Product Research, Cell Therapy. Responsibilities are design and implementation of research protocols for cell based therapies in neurological diseases. The scope of the position includes regulatory interactions, selection of contractors, project design and management, presentation to internal board members and potential corporate partners.

1996 - 1999 **THERACELL, INC.,** Somerville, New Jersey

Director of Product Research. Responsibilities are design and implementation of research protocols for cell based therapies in neurological diseases. The scope of the position includes regulatory interactions, selection of contractors, project design and management, presentation to internal board members and potential corporate partners.

1976-1996 **HOECHST ROUSSEL PHARMACEUTICALS, INC.,** Somerville, New Jersey

91-96 ***Director Biological Research***, (93-96); ***Acting Director,*** (91-93). Direct a research department of 48 scientists (eleven Ph.D.s), and a budget of $5.4 million. Direct multiple project teams, six drug discovery and exploratory teams, as well as the direction of a cardiovascular group that supports neuroscience research and a New Leads laboratory. Direct responsibility for cost center, development of budgets, control of expenditures, and management of personnel issues).

- Member of Research Team along with Directors of Chemistry and Molecular Neurobiology, and responsible for Pharmacology sections of INDs and NDAs.
- Over four year period, screened 2,500 compounds in two major disease areas, Alzheimer's and schizophrenia. This activity resulted in ten lead compounds, seven early development, three GLP TOX candidates and produced an IND.
- Member of key committees including Neuroscience Operating Committee, Neuroscience Strategy Team, Neuroscience Pre Clinical Drug Development Committee, Licensing Opportunity Review Team, and various strategic implementation and policy groups.

- Under my direction, the professional staff has been well represented in professional presentations and publication in first and second tier journals. For I993 and I994, we had 24 papers published.

90-91 ***Associate Director, Department of Biological Research.*** Direct the activities of 31 scientists (includes eight Ph.D.s) and a $3.3 million budget. Responsible for project team coordination in compound screening, compound selection, and research direction as well as personnel management, quality value management, safety management and interdisciplinary and interdepartmental interactions.

- Served as co-chairman on four drug development project teams and prepared the Pharmacology sections for the four INDs. All four compounds now in clinical trials.

88-90 ***Research Group Manager, Department of Biological Research.*** Direct activities of 18 scientists (5 Ph.D.s and 13 lower-level pharmacologists), and a budget of $2 million in neuropharmacology, behavioral pharmacology, and analgesics. Responsibilities included preparation of INDs and participation in project committee meetings with clinicians involved in Phase I and II of drug development. Prepared Pharmacology sections of two INDs.

85-88 ***Group Leader, Department of Pharmacology***, (86-87); ***Senior Research Associate***, (85-86). Responsible for managing group of 14 including 4 Ph.D.s and for the development of Alzheimer's assays and compounds, and development of the antipsychotic program.

- Expanded and further developed the atypical neuroleptics area, making it a highly sophisticated program for the development of site-specific antipsychotic agents. Also developed the evoked-potential system, dark avoidance and enhancement of memory assays.

82-85 ***Research Associate, Department of Biological Sciences.*** Responsible for laboratory experiments in the area of neuropharmacology. Supervised four pharmacologists.

- Expand4d and further developed the atypical neuroleptics area, making it a highly sophisticated program for the development of site-specific antipsychotic agents.

- Developed the evoked potential system, dark avoidance and enhancement of memory assays, resulting in two clinical candidates for the treatment of Alzheimer's disease.

76-82 ***Senior Research Pharmacologist, Department of Biological Services.*** Responsible for laboratory experiments in the area of neuropharmacology. Supervised two pharmacologists.

1970-1976 **CIBA-GEIGY CORPORATION,** Summit, New Jersey

75-76 ***Supervisor of Psychopharmacology Section.*** Supervised basic research in the area of psychopharmacological methodology with a concentration on the development of models for depression and schizophrenia useful for drug evaluation.

70-75 ***Head of Electrophysiology, Psychopharmacology Section.*** Major responsibilities and objectives were to design and implement an electroencephalographic evaluation of drugs in the primate, to initiate a self-stimulation program in the rat which was used for the evaluation of neuroleptics, and to do basic research in the area of the psychopharmacology to both graduate and under-graduate studens.

1970-1976 **Farleigh Dickinson University,** Madison, New Jersey. ***Lecturer***. Department of Psychology. While fully employed at Ciba-Geigy, taught psychology, physiological psychology, and psychopharmacology to both graduate and undergraduate students.

EDUCATION	**Villanova University,** Villanova, Pennsylvania
1970	Completed all course work, **(ABD) for M.S. in Psychology**. Graduate Assistantship. Taught laboratory section of Experimental Perception. Assisted in teaching Abnormal Psychology, and teaching research in Social Psychology and Lab assistant in Physiological Psychology.
1968	**B.A.**, Psychology.
PUBLICATIONS	Extensive list of Publications and Abstracts attached.
PROFESSIONAL MEMBERSHIPS	American Association for the Achievement of Science American College of Neuropharmacology and Psychiatry (Corporate Member) New York Academy of Sciences Society for Neuroscience American Society for Transplantation and Repair (ASNTR)
PERSONAL	Married, family.

Curriculum Vitae
Michael L. Cornfeldt

PUBLICATIONS and ABSTRACTS

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Michael L. Cornfeldt

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Curriculum Vitae
Michael L. Cornfeldt

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